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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,282	06/25/2003	Nathalie Bamas-Jacques	FRAV2002/0013 US NP	4452

5487 7590 01/21/2009

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EXAMINER	
SAIDHA, TEKCHAND	

ART UNIT	PAPER NUMBER
1652	

NOTIFICATION DATE	DELIVERY MODE
01/21/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/603,282	BAMAS-JACQUES ET AL.	
	Examiner	Art Unit	
	Tekchand Saidha	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11,13,15-17,19-26, 29-35 and 40-42* is/are pending in the application.

4a) Of the above claim(s) *2-4,17,19-26,29-35 and 40-42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5-11,13,15 and 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/9/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Art Unit and the Examiner for this application are changed. Please make a note of it. In presenting the claims, especially if a claim is canceled, Applicants are advised not to rewrite the canceled claim.

2. ***Election***

Applicant's election of Group XI (claims 5-8, 11, 15-16 ~~& 41~~), drawn to nucleic acid variants with G828A & C658T, with traverse is acknowledged. Claim 41 is regrouped with groups IV, V or VI as being drawn to a variant polypeptide (see explanation below).

Applicants respectfully traverse the restriction requirement with regards to Groups IX, X, XI, XV, XVI and XVII for the reasons stated below.

For a Restriction Requirement to be proper, "there are two criteria for restriction among patentably distinct inventions: (1) The inventions must be independent...or distinct as claimed...and (2) There must be a serious burden on the examiner if restriction is not required." (MPEP §803).

According to the interpretation provided in MPEP §802.01, the term "independent" means that "there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation or effect...". The term "distinct" is defined in MPEP §801.02 as meaning that "two or more subjects as disclosed are related.., but are capable of separate manufacture, use or sale as claimed, and ARE PATENTABLE (novel and unobvious) OVER EACH OTHER..." The above cited language of 35 USC §121 is clear in that the requirement to restrict an application to one of the inventions disclosed therein is proper only if the disclosed inventions are both independent and distinct.

While Applicants take no position on the patentable distinctness of Groups IX, X, XI, XV, XVI and XVII, Applicants submit that the claims of Group IX, X, X1, XV, XVI and XVII are not independent and are so linked as to form a single general inventive concept. In particular, Group XI is drawn to a nucleic acid variant with G828A and C658T, while Group IX is drawn to the sequence but having the nucleic acid variant

C658T and Group X is drawn to the same sequence but having the nucleic acid variant G828A.

Moreover, Applicants submit that a search of Groups IX, X and XI would not be an undue burden on the Examiner. A search of Group XI would necessarily include a search of the nucleic acid in Groups IX and X since this is the same nucleic acid except for the C658T and G828A substitutions. Therefore, Applicants maintain that the claims of Groups IX, X and XI should be examined together in the interest of compact prosecution of the instant application.

Further, once the search is performed for Groups IX, X and XI the search would necessarily cover subject matter claims of Groups XV, XVI and XVII. Claims of Groups IX, X, X1 are drawn to nucleic acid variants of the same sequence while Groups XV, XVI and XVII are drawn to the method wherein a Streptomyces strain comprises the afore-mentioned nucleic acid variants. A search of the nucleic acids of Groups IX, X and XI would necessarily include a search of using the afore-mentioned variants to attain a bacterial strain. It is respectfully submitted that it would not be an undue burden to include the nucleic acid variants and the methods of using said nucleic acid variants at the same time.

For the above reasons, Applicants respectfully request the Examiner to reconsider and withdraw the Restriction Requirement with regards to Groups IX, X, XI, XV, XVI and XVII.

Applicants' arguments are considered and found to be partly persuasive with respect to combining Groups IX, X & XI, drawn to the variant nucleic acid G828A & C658T. According these groups representing claims 5-11, 13 & 15-16, drawn to nucleic acid mutants G828A & C658T, vector & host cell will be considered in this examination.

Claim 41 is a variant polypeptide (not the variant encoded by nucleic acid variant G828A & C658T) and is therefore regrouped with group IV, V or VI.

However, the inventions of groups XV, XVI and XVII, drawn to method claims which do not specifically use the nucleic acid mutants of G828A & C658T are distinct independent inventions and are not so linked as to form a single general inventive concept as previously explained. Searching the specific nucleic acid mutants will not

necessarily lead to art to the method claims of groups XV, XVI & XVIII. The search is not co-extensive and is therefore burdensome to combine the various groups as argued by the Applicants. Searching the inventions of Groups IX, X, XI, XV, XVI and XVII together would impose serious search burden.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

Because of the regrouping of claim 41, the LOU determination is not made final yet.

3. Claims 5-11, 13 & 15-16, drawn to nucleic acid mutants G828A & C658T, vector & host cell are under consideration in this examination.

4. **Claims withdrawn**:

Claims 2-4, 17, 19-26, 29-35 & 40-42 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on 6/28/2002. It is noted, however, that applicant has not filed a certified copy of the foreign application as required by 35 U.S.C. 119(b).

6. ***Sequence Rules***

The instant specification, Figure &, present nucleic acid/amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), but fails to comply with the requirements. According to 37 CFR 1.821-825, every disclosed amino acid sequence of four or more residues or 10 or more nucleotides must be identified by a SEQ ID NO. The amino acid

or nucleic acid sequences presented do not have SEQ ID NOs. In order to comply with the sequence rules Applicants must identify these sequences by providing SEQ ID NO:, and where required provide a new version of the sequence listing and disk.

Applicant must submit a CRF copy and paper copy of the Sequence Listing, a statement that the content of the paper and computer readable copies are the same and where applicable include no new matter as required by 37 C.F.R. j 1.821(e) or 1.821(9 or 1.821(g) or 1 .825(d), as well as an amendment directing its entry into the specification.

Note: If the nucleic acid and the encoded amino acid sequences of Figure 7 are already present in the sequence listing filed 12/15/2003, Applicants may amend the brief description to drawings (or legend to Figure 7) by the inserting the appropriate sequence identifier numbers.

7. ***Specification***

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

8. ***Claim Objections***

Claims 5-8 and 13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The claim(s) depend from claim(s) reciting non-elected subjected matter. Appropriate correction is required.

Claim 16 recite – ATCC numbers, viz., ATCC12019, ATCC27455, ATCC15297 and ATCC 11415, which is an improper incorporation by reference.

9. ***Claim Rejections - 35 USC § 112*** (first paragraph)

Written Description

Claims 5-8, 11, 15-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are drawn to variants of nucleic acid(s), which (i) either directly or indirectly refer to specific mutant positions with no reference sequence and (ii) and therefore no defined structure and (iii) with no defined function or activity.

The specification discloses the DNA sequence of SEQ ID No. 1 encoding an N-methyltransferase enzyme of SEQ ID NO: 2. However, without a reference sequence for the variants and the assigned function, the claims lack the required written description. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

10. ***Claim Rejections - 35 USC § 112*** (second paragraph)

Claim 5-11, 13 & 15-16 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

These claims are drawn to variants of nucleic acid(s), which either directly or indirectly refer to specific mutant substitutions with no reference sequence. The claims are unclear for lack of the corresponding reference sequence.

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached between 8.30 am - 5.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat T. Nashed can be reached on (571) 272 0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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January 14, 2009